



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2020-0693; FRL-10021-09]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; Pesticide Data-Call-In Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on an Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB). The ICR, entitled “Pesticide Data-Call-In Program” and identified by EPA ICR No. 2288.04 and OMB Control No. 2070-0174, represents the renewal of an existing ICR that is scheduled to expire on November 30, 2021. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting public comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be submitted on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2020-0693, by using the *Federal eRulemaking Portal* at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information

on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Mission Support Division, Office of Program Support, (P75601), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 347-1249; email address: siu.carolyn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Information Collection Activity or ICR Does this Action Apply to?

Title: Pesticide Data-Call-In Program

ICR number: EPA ICR No. 2288.04.

OMB control number: OMB Control No. 2070-0174.

ICR status: This ICR is currently scheduled to expire on November 30, 2021. An Agency

may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the *Federal Register* when approved, are listed in 40 CFR part 9, are displayed either by publication in the *Federal Register* or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR covers the information collection activities associated with the issuance of data-call-ins (DCIs) under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA regulates the use of pesticides under the authority of two federal statutes: FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a. In general, before manufacturers can sell pesticides in the United States, EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards to protect human health and the environment. EPA grants a "registration" or license that permits a pesticide's distribution, sale, and use only after the company meets the scientific and regulatory requirements.

In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with the use of the product. Applicants, or potential registrants, must generate or provide the scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide. The data allow EPA to evaluate whether a pesticide has the potential to cause harmful effects on certain non-target organisms and endangered species (including humans, wildlife, and plants) and on surface water or ground water.

Through a rigorous scientific and public process, EPA specifies the kinds of data and information necessary to make regulatory judgments about the risks and benefits of pesticide products under FIFRA sections 3, 4 and 5, as well as the data and information needed to

determine the safety of pesticide chemical residues under FFDCA section 408. The regulations in 40 CFR part 158 describe the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process (e.g., as used in the registration review program); or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

As described in 40 CFR 158.30, however, FIFRA provides EPA with flexibility to require, or not require, data and information for the purposes of making regulatory judgments for individual pesticide products, thereby allowing for the data required to be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process. In addition, the Agency cautions applicants that the data routinely required by the regulations may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment. EPA may, therefore, require the submission of additional data or information beyond that specified in the regulations if such data or information are needed to evaluate a pesticide product as required by FIFRA and FFDCA.

EPA uses the DCIs issued under this ICR to acquire the data that has been deemed necessary for the Agency's statutorily mandated review of a pesticide's registration, which require it to assess whether the continued registration of an existing pesticide causes an unreasonable adverse effect on human health or the environment and whether the Agency will pursue appropriate regulatory measures. The key program areas are described in more detail in this ICR, along with the Agency's estimates of the information collection burden and costs associated with issuing DCIs under those key program areas.

Form numbers: EPA For No. 8570-4, 8574-27, 8570-28, 8570-32, 8579-34, 8570-35, 8570-36, 8570-37, 6300-3, and 6300-4.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 20 and 8182 hours per response, depending on the details associated with the individual DCIs. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected by this ICR are pesticide registrants and are identified by the North American Industrial Classification System (NAICS) code 325320, Pesticide and Other Agricultural Chemical Manufacturing.

Respondent's obligation to respond: Mandatory under FIFRA section 3(c)(2)(B).

Estimated total number of potential respondents: 122.

Frequency of response: On occasion.

Estimated total annual burden hours: 1,091,617 hours.

Estimated total annual cost: \$84,846,448.

III. Are There Changes in the Estimates from the Last Approval?

There is an increase of 465,948 hours in the total estimated respondent burden compared with that identified in the ICR that was approved by OMB. This increase reflects EPA's correction of a clerical error associated with the approved hours entered into the tracking system (causing a burden of 58,206 hours to be approved rather than the 625,669 burden hours requested in the submitted ICR), and an increase in the estimated DCIs issued over the next three years from 663 to 802 that will require data generation thus raising the average of DCIs issued annually from 221 to 267. Other factors include the addition of high-test costs for certain DCIs, and an increase in non-government wage rates. This increase qualifies as an adjustment.

In addition, OMB has requested that EPA move towards using the 18-question format for ICR Supporting Statements used by other federal agencies and departments and is based on the

submission instructions established by OMB in 1995, replacing the alternate format developed by EPA and OMB prior to 1995. EPA intends to update this Supporting Statement during the comment period to reflect the 18-question format, and has included the questions in an attachment to this Supporting Statement. In doing so, the Agency does not expect the change in format to result in substantive changes to the information collection activities or related estimated burden and costs.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: March 25, 2021.

Michal Freedhoff,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2021-06608 Filed: 3/30/2021 8:45 am; Publication Date: 3/31/2021]